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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,204	07/30/2003	Shanta M. Modak	A33459-PCT-USA-A (070050.	3145
21003	7590	04/04/2005	EXAMINER	
BAKER & BOTTS 30 ROCKEFELLER PLAZA NEW YORK, NY 10112			CHOI, FRANK I	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 04/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/633,204	Applicant(s) MODAK ET AL.	
	Examiner Frank I. Choi	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,7-16,19-31,33-37 and 39 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4,7-16,19-31,33-37 and 39 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/30/2002</u> | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4,7-16, 19-31,33-37, 39 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of US Pat. 6,582,719 or Claims 1-55 of US Pat. 6,106,505, each in view of WO 97/25085, Darouische et al. (US Pat. 6,719,991 or US Pat. 5,624,704), Raad et al. (US Pat. 5,688,516) and Domenico et al. (Journal of Antimicrobial Chemotherapy (1991)).

Claims 1-15 of US Pat. 6,582,719 claim an anti-infective medical article prepared by exposing a polymer-containing medical article, such as a intravascular catheter, with 1-8% minocycline, 1-8% chlorihexidine free base or chlorhexidine diacetate, 0.5-2% bismuth nitrate, 0.2-1.0% benzalkonium chloride, and 25-300 micrograms/cm of silver sulfadiazine or silver carbonate (Claims 1-15).

Claims 1-55 of US Pat. 6,106,505 claim polymeric medical article, such as a intravenous catheter, which is impregnated with chlorhexidine free base, triclosan and silver sulfadiazine (Claims 1-55).

WO 97/25085 disclose treating vascular catheters with chlorhexidine, such as chlorhexidine free base, diacetate, digluconate, and triclosan (pgs. 5,6). It is disclosed additional anti-infective agents such as silver sulfadiazine and benzalkonium chloride can also be added (Pg. 14, lines 3-9).

Darouiche et al. ('991) disclose the combination of an antibiotic, such as minocycline, and antiseptic, such as chlorhexidine, triclosan or silver, for coating catheters (Column 4, lines 6-27, column 7, lines 8-36, Column 8, lines 16-35).

Darouiche et al. ('704) disclose the combination of an antibiotic, such as minocycline, and antiseptic, such as chlorhexidine or triclosan, for coating catheters (Column 4, lines 54-60, Column 5, lines 3,4, 16,17,19,25-35, column 6, lines 5-13, 48-68)

Raad et al. disclose that chelating agents, such as zinc citrate and citrate and bismuth, inhibit the formation of glycocalyx produced by staphylococci and Candida which glycocalyx helps said organisms adhere and stick to catheter surfaces (Column 1, lines 60-68, Column 2, lines 1-11, Column 4, lines 44,48,49,65,66). It is disclosed that a tetracycline antibiotic, such as minocycline which is effective in killing adherent staphylococci embedded in glycocalyx, is combined with said chelating agent and coated on the medical device (Column 6, lines 2-13, 40-50, Claims 1,2,9,10,11,14-17).

Domenic et al. disclose that bismuth nitrate and bismuth subsalicylate are effective in inhibiting capsular polysaccharide production by bacteria which forms bacterial biofilm (Pg. 808).

The difference between the claimed invention and the claims of US Pat 6,582,719 is that said US Patent does not expressly claim the use of bismuth citrate or bismuth salicylate,

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chlorhexidine gluconate, triclosan or a zinc salt. The difference between the claimed invention and the claims of US Pat 6,106,505 is that said US Patent does not expressly claim the use of minocycline, bismuth citrate or bismuth salicylate, chlorhexidine gluconate, benzalkonium chloride or a zinc salt. However, the prior art amply suggest the same as the prior art discloses that chlorhexidine, such as chlorhexidine digluconate, can be combined with triclosan and benzalkonium chloride, that minocycline can be combined with chelating agents such as zinc citrate and citrate and bismuth, that bismuth nitrate and bismuth subsalicylate are effective in inhibiting the formation of capsular polysaccharide by bacteria which forms bacterial biofilm, and that minocycline can be combined with chlorhexidine or triclosan. As such, it would have been well within the skill of to modify the prior art as above with the expectation that any chlorhexidine salt, including chlorhexidine gluconate in combination with triclosan, minocycline and benzalkonium chloride would be suitable for coating a catheter, that zinc citrate or citrate and bismuth in combination with minocycline would be effective in killing bacteria on catheters and inhibiting the formation of glycocalyx, and that bismuth salicylate or bismuth citrate could be used instead of bismuth nitrate or in combination with bismuth nitrate to inhibit the formation of glycocalyx or biofilm.

Therefore, the claimed invention, as a whole, would have been an obvious modification of the claims of US Pat. 6,582,719 or of the claims of US Pat. 6,106,505 to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of said claims and references.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4,7-16, 19-31,33-37, 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raad et al. (US Pat. 5,688,516) in view of Darouische et al. (US Pat. 6,719,991 or US Pat. 5,624,704), WO 97/25085 and Domenico et al. (Journal of Antimicrobial Chemotherapy (1991)).

Raad et al. disclose that chelating agents, such as zinc citrate and citrate and bismuth, inhibit the formation of glycocalyx produced by staphylococci and Candida which glycocalyx helps said organisms adhere and stick to catheter surfaces (Column 1, lines 60-68, Column 2, lines 1-11, Column 4, lines 44,48,49,65,66). It is disclosed that a tetracycline antibiotic, such as minocycline which is effective in killing adherent staphylococci embedded in glycocalyx, is combined with said chelating agent and coated on the medical device (Column 6, lines 2-13, 40-50, Claims 1,2,9,10,11,14-17).

Darouiche et al. ('991) disclose the combination of an antibiotic, such as minocycline, and antiseptic, such as chlorhexidine, triclosan or silver, for coating catheters (Column 4, lines 6-27, column 7, lines 8-36, Column 8, lines 16-35).

Darouiche et al. ('704) disclose the combination of an antibiotic, such as minocycline, and antiseptic, such as chlorhexidine or triclosan, for coating catheters (Column 4, lines 54-60, Column 5, lines 3,4, 16,17,19,25-35, column 6, lines 5-13, 48-68)

WO 97/25085 disclose treating vascular catheters with chlorhexidine, such as chlorhexidine free base, diacetate, digluconate, and triclosan (pgs. 5,6). It is disclosed additional anti-infective agents such as silver sulfadiazine and benzalkonium chloride can also be added (Pg. 14, lines 3-9).

Domenic et al. disclose that bismuth nitrate and bismuth subsalicylate are effective in inhibiting capsular polysaccharide production by bacteria which forms bacterial biofilm (Pg. 808).

The difference between the claimed invention and the prior art is that the prior art does not expressly disclose the combination of minocycline and chlorhexidine, the combination of minocycline, triclosan and bismuth, or minocycline and bismuth for treating a polymeric-containing medical article. However, the prior art amply suggest the same as the prior art discloses that chlorhexidine, such as chlorhexidine digluconate, can be combined with triclosan, that minocycline can be combined with chelating agents such as zinc citrate and citrate and bismuth, that bismuth nitrate and bismuth subsalicylate are effective in inhibiting the formation of capsular polysaccharide by bacteria which forms bacterial biofilm, that minocycline can be combined with triclosan or chlorhexidine and that chlorhexidine can be combined with triclosan, silver sulfadiazine or benzalkonium chloride. As such, it would have been well within the skill of to modify the prior art as above with the expectation that any chlorhexidine salt, including chlorhexidine gluconate in combination with triclosan would be suitable for coating a catheter, that zinc citrate or citrate and bismuth in combination with minocycline would be effective in killing bacteria on catheters and inhibiting the formation of glycocalyx, that bismuth salicylate or bismuth citrate could be used instead of bismuth nitrate or in combination with bismuth nitrate to

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inhibit the formation of glycocalyx or biofilm, that silver sulfadiazine or benzalkonium chloride can be combined with chlorhexidine and triclosan for treating catheters and that minocycline can be combined with chlorhexidine and triclosan for treating catheters.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

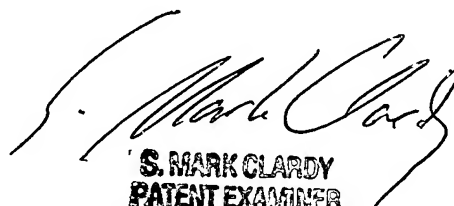
A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Gary Kunz, can be reached at 571-272-0887. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

FIC 3/20/05



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